Part I: Medicare Reviews

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NOTE: Summaries of OIG audit and evaluation reports in this publication contain rounded figures. Monetary amounts in case narratives are rounded to the next lower dollar, where appropriate.

Part I: Medicare Reviews

Medicare Part A and Part B

Hospitals:

Medicare > Hospitals > Inpatient Psychiatric Facilities

Emergency Department Adjustments for Inpatient Psychiatric Facilities

Based on our sample results, we estimated that Medicare contractors made \$1.7 million in Part A overpayments to hospital-based inpatient psychiatric facilities (IPF) for calendar years (CY) 2006 and 2007 on behalf of beneficiaries who had been admitted to the IPFs upon discharge from the acute-care section of the same hospital. Our review found that hospital-based IPFs incorrectly coded the source of admission on 75 of 100 sampled claims. As a result, Medicare contractors made \$3,000 in overpayments to the IPFs for the emergency department services in our sample.

The Centers for Medicare & Medicaid Services (CMS) makes an additional Medicare payment to an IPF for the first day of a beneficiary's stay to account for emergency department costs. However, CMS does not make this payment if the beneficiary was discharged from the acute-care section of a hospital to its hospital-based IPF. Hospitals must enter the correct code on their Medicare claim forms to ensure that the hospital-based IPF does not receive an additional payment for the costs of emergency department services that Medicare covers in its payment to the acute-care hospital.

We recommended that CMS (1) instruct its Medicare contractors to recover the \$3,000 in overpayments for the sampled claims; (2) instruct its Medicare contractors to immediately reopen the nonsampled claims, review our information on these claims (which have overpayments estimated at \$1.7 million), and recover any overpayments; (3) instruct its Medicare contractors to emphasize to hospital-based IPFs the importance of using the correct code to identify beneficiaries who were discharged from the acute-care section of the same hospital; (4) establish edits in the Common Working File (CWF) to prevent and detect overpayments to IPFs that use incorrect source-of-admission codes on claims; and (5) consider conducting periodic postpayment reviews of claims submitted after our review to identify any claims that were billed and paid with incorrect source-of-admission codes. CMS concurred with our recommendations and described the corrective actions that it was taking or planned to take. (A-01-09-00504)

Medicare > Hospitals > Inpatient Psychiatric Facilities

Payments for Interrupted Stays at Inpatient Psychiatric Facilities

Based on a sample of 100 claims, we estimated that Medicare fiscal intermediaries (FI) made \$3.9 million in improper payments to IPFs nationwide in CYs 2006 and 2007 for claims on behalf of beneficiaries who had been discharged from another IPF within the prior 3 days. To discourage inappropriate discharges and readmissions to IPFs, CMS has established a 3-day policy for interrupted stays. An interrupted stay occurs when a beneficiary is discharged from an IPF and admitted to the same or a different IPF within 3 consecutive days. In such a case, the "readmission" is considered a continuation of the initial stay. CMS provides an exception to the 3-day policy when the beneficiary is admitted to a different IPF within 3 days and the second IPF is unaware of the beneficiary's immediately preceding stay in the first IPF.

We recommended that CMS (1) instruct its FIs to recover \$19,000 for the 75 sampled claims with payment errors; (2) review our information on the unsampled claims for IPF interrupted stays, which had potential overpayments estimated at \$3.8 million, and work with its FIs to recover any overpayments; (3) establish system edits to prevent and detect overpayments to IPFs that admitted beneficiaries from another IPF and did not bill the claim as part of an interrupted stay; (4) instruct its FIs to initiate the necessary system modifications to process and pay IPF interrupted stays correctly; (5) consider reviewing claims submitted after our review to identify any incorrectly paid claims; and (6) revise its billing instructions to address appropriate billing for the second part of interrupted stays involving two separate IPFs when the second IPF is aware of the preceding stay. CMS concurred with our recommendations. (A-01-09-00508)

Medicare > **Hospitals** > **Inpatient Rehabilitation Facilities**

Inpatient Rehabilitation Facilities' Compliance With Medicare's Transfer Regulation

Inpatient rehabilitation facilities (IRF) did not always code claims in compliance with Medicare's transfer regulation during fiscal years (FY) 2004 through 2007. Pursuant to Medicare's transfer regulation, Medicare pays the full prospective payment to an IRF that discharges a beneficiary to home. In contrast, Medicare pays a lesser amount for a transfer case. Whether Medicare pays for a discharge to home or a transfer depends on the patient status code indicated on the IRF's claim. On April 1, 2007, in response to our prior recommendations, CMS implemented an edit in the CWF to identify transfers improperly coded as discharges.

Of the 220 claims in our sample, 213 claims pertained to transfers to facilities that were subject to Medicare's transfer regulation but were improperly coded as discharges. These 213 claims resulted in overpayments of \$1.2 million. Based on our sample results, we estimated that FIs overpaid \$34 million to IRFs for the 4-year period that ended September 30, 2007. Also, even though the new CWF edit detected miscoded claims, FIs did not take appropriate action to adjust the claims and prevent incorrect payments.

We recommended that CMS (1) recover the \$1.2 million in overpayments identified in our sample, (2) instruct FIs to review the unsampled claims and identify and recover additional overpayments estimated at \$32.8 million, (3) instruct FIs to take appropriate action in response to future CWF edit alerts, (4) follow up with FIs to ensure that they took appropriate action in response to CWF edit alerts, and (5) consider reviewing claims paid after our audit period to identify any improperly coded transfers. CMS agreed with our recommendations and described the corrective actions that it planned to take. (A-04-09-00059)

Medicare > Hospitals > Inpatient Rehabilitation Facilities

Inpatient Rehabilitation Facilities' Transmission of Patient Assessment Instruments

IRFs did not always receive reduced case-mix-group payments for claims with patient assessment instruments that were transmitted to CMS's National Assessment Collection Database (the Database) more than 27 days after the beneficiaries' discharges. To administer the prospective payment system, CMS requires IRFs to electronically transmit a patient assessment instrument for each IRF stay to the Database, which the Iowa Foundation for Medical Care (the Foundation) maintains. If an IRF transmits the instrument more than 27 calendar days from (and including) the beneficiary's discharge date, the IRF''s payment rate for the applicable case-mix group should be reduced by 25 percent.

We found that IRFs did not receive reduced case-mix-group payments for 113 of the 200 sampled claims with patient assessment instruments that were transmitted to the Database after the 27-day deadline. Based on these sample results, we estimated that FIs made \$20.2 million in overpayments to IRFs for dates of service in calendar years 2006 and 2007. Additionally, for 79 claims, IRFs initially transmitted patient assessment instruments to the Database within the 27-day deadline but subsequently retransmitted these instruments after the deadline to correct errors. CMS guidance does not address the applicability of the 25-percent penalty in these situations. We estimated that FIs may have made an additional \$19 million in overpayments to IRFs for claims with these instrument retransmissions.

We recommended that CMS (1) adjust the 113 sampled claims for overpayments of \$424,000; (2) determine whether any of the \$323,000 potential payment penalty should apply to the 79 sampled claims with modified patient assessment instruments that were transmitted after the 27-day deadline; (3) immediately reopen the nonsampled claims, review our information on these claims (which have overpayments estimated at \$19.8 million and set-aside payments estimated at \$18.7 million), and recover any overpayments; (4) alert IRFs to the importance of reporting the correct patient assessment instrument transmission dates on their claims; (5) consider establishing a process that would allow the Fiscal Intermediary Shared System (FISS) to interface with the Database to identify, on a prepayment basis, IRF claims with incorrect patient assessment instrument transmission dates; (6) ensure that FIs have access to Foundation reports that document late or missing patient assessment instrument transmissions and use these reports to conduct periodic postpayment reviews; (7) revise the FISS edit to count the discharge date as day 1 in the 27-day counting sequence used to apply the 25-percent

payment penalty; and (8) establish written policies to address whether patient assessment instruments that are retransmitted after the 27-day deadline to correct errors in the initial timely transmissions are subject to the 25-percent payment penalty. CMS concurred with our recommendations and described the steps that it had taken or planned to take to address the issues we identified. (A-01-09-00507)

Medicare > Hospitals > Inpatient Services Payments

High-Dollar Payments for Inpatient Services

Of the 415 high-dollar Medicare Part A payments (\$200,000 or more) that a Medicare contractor made to hospitals for inpatient services for CYs 2003 through 2005, 306 were appropriate. The 109 remaining payments included net overpayments totaling \$3 million. At the start of our audit, hospitals had not refunded \$1.9 million of these net overpayments.

Contrary to Federal guidance, hospitals inaccurately reported the number of billing units of service, reported incorrect procedure codes, and reported excessive charges that resulted in inappropriate outlier payments. Hospitals attributed most of the incorrect claims to clerical errors or to billing systems that could not prevent or detect the incorrect billing of units of service and other types of billing errors. The contractor made these incorrect payments because neither the FISS nor the CWF had sufficient edits in place to prevent or detect incorrect payments.

We recommended that the contractor (1) recover the \$1.9 million in net overpayments, (2) determine and recover the overpayment for one inpatient claim still under adjudication, (3) use the results of this audit in its provider education activities, and (4) consider implementing controls to identify and review all payments greater than \$200,000 for inpatient services. The contractor concurred with our recommendations and described corrective actions that it had taken or planned to take. (A-07-09-04148)

Medicare > Hospitals > Outpatient Services Payments

High-Dollar Payments for Outpatient Services

Of the 104 high-dollar Medicare Part B payments (\$50,000 or more) that a Medicare contractor made to hospitals for outpatient services for CYs 2003 through 2005, 27 were appropriate. The 77 remaining payments included overpayments totaling \$6.1 million. At the start of our audit, hospitals had not refunded \$2.2 million of the overpayments.

The hospitals attributed the incorrect payments to clerical errors or to billing systems that could not prevent or detect the incorrect billing of units of service and other types of billing errors. The contractor made these incorrect payments because neither the FISS nor the CWF had sufficient edits in place during CYs 2003 through 2005 to prevent or detect the overpayments.

We recommended that the contractor recover the \$2.2 million in identified overpayments and use the results of this audit in its provider education activities. The contractor concurred with our recommendations and described its corrective actions. (A-07-10-04154)

Nursing Homes:

Medicare > Nursing Homes > Part B Services

Part B Mental Health Services During Non-Part A Nursing Home Stays

Based on a medical review, we found that 39 percent of claims for mental health services that Medicare Part B allowed during non-Part A nursing home stays in 2006 did not meet the program requirements for coverage. Specifically, services were medically unnecessary, undocumented or inadequately documented, or miscoded. These errors resulted in an estimated \$74 million in inappropriate Part B payments, of the \$211 million allowed in 2006. Claims for psychotherapy services made up the majority of these inappropriately paid claims, which is consistent with findings from the CMS 2006 Comprehensive Error Rate Testing (CERT) report.

Non-Part A stays occur in nursing homes when the stay is not paid for under the Medicare Part A skilled nursing facility benefit. If the beneficiary's nursing home stay is not covered under Part A, Part B may still provide coverage for mental health services provided during the stay. We also found that 71 percent of the sampled mental health claims contained inaccurate diagnosis codes or lacked adequate documentation to support diagnosis codes, although these codes did not directly affect reimbursement. No recommendations were made in the report. (OEI-06-06-00580)

Medicare > Nursing Homes > Part B Services

Part B Enteral Nutrition Therapy Services During Non-Part A Nursing Home Stays

Based on a medical review of Medicare Part B enteral nutrition therapy (ENT) claims for ENT provided during non-Part A nursing home stays in 2006, we found that 21 percent of the claims were either inappropriate (5 percent) or inadequately documented (16 percent). The errors resulted in an estimated \$39 million in inappropriate Part B payments among the \$284 million allowed for all ENT claims during non-Part A nursing home stays in 2006. Claims for pumps and pump supply kits represented 70 percent of the inadequately documented sampled services.

Non-Part A stays occur in nursing homes where the stay is not paid for under the Medicare Part A skilled nursing facility benefit. If a beneficiary's nursing home stay is not covered under Part A, Part B may still provide coverage for ENT provided during the stay.

We also found that 13 percent of the allowed ENT claims associated with pumps were questionable. Although these claims met contractors' payment and coverage guidelines for

slow delivery rates of less than 100 millimeters per hour, residents' medical records did not include medical conditions (e.g., diabetes, risk of aspiration, or fluctuating glucose levels) that justified the need for the more expensive pump delivery method over the gravity method, which could provide for a slow rate. Medicare contractor payment and coverage guidelines do not require the documentation of a medical condition specifically justifying pump use over the gravity method when a slow rate of administration is indicated. No recommendations were made. (OEI-06-07-00090)

Practitioners and Suppliers:

Medicare > Practitioners and Suppliers > Physicians

Place-of-Service Coding for Physician Services

We found that physicians did not always correctly code nonfacility places of service on Medicare Part B claims. Based on our sample results, we estimated that Medicare contractors nationwide overpaid physicians \$13.8 million for incorrectly coded services provided during CY 2007. To account for the increased overhead expense that physicians incur by performing services in nonfacility locations, such as physicians' offices, Medicare reimburses physicians at a higher rate for certain services performed in these locations and at a lower rate for services performed in facility settings, such as hospital outpatient departments or ambulatory surgical centers. Physicians are required to identify the place of service on the health insurance claim forms that they submit to Medicare contractors. However, for 90 of the 100 services in our sample, physicians used nonfacility place-of-service codes on their claims for services that were actually performed in hospital outpatient departments or ambulatory surgical centers.

We recommended that CMS instruct its Medicare contractors to (1) recover \$4,700 in overpayments for the sampled services; (2) immediately reopen the claims associated with the nonsampled services, review our information on these claims (which had estimated overpayments of \$13.8 million), and work with the physicians who provided the services to recover any overpayments; (3) continue to strengthen their education process and reemphasize to physicians and their billing agents the importance of correctly coding the place of service; and (4) continue to work with program safeguard contractors (PSC) and other Medicare contractors to develop a data match that will identify physician services at high risk for place-of-service miscoding and recover any identified overpayments. CMS concurred with our recommendations and described the corrective actions that it was taking or planned to take. (A-01-09-00503)

Medicare > Practitioners and Suppliers > Physicians

Questionable Billing for Physician Services for Hospice Beneficiaries

Questionable billing for Part B physician services provided to hospice beneficiaries amounted to nearly \$566,000 in 2009. This means that Medicare paid this amount to physicians directly through Part B for services related to a beneficiary's terminal illness, while Medicare also paid for services from the same physician for the terminal illness under Part A. Although we did not find that this problem is widespread, billing for physician services for hospice care is a potential program vulnerability given that Medicare may be billed under Part A and Part B.

The Medicare hospice benefit allows a beneficiary with a terminal illness to forgo curative treatment for the illness and instead receive palliative care, which is the relief of pain and other uncomfortable symptoms. Medicare pays for physician services through Part A or Part B, depending on a physician's relationship with the hospice. If a beneficiary's attending physician is an employee or under contract with the hospice provider, Medicare pays the hospice for physician services under Part A, and the hospice compensates the physician through salary or some other arrangement. If a beneficiary's attending physician is not an employee or under contract with the hospice provider, Medicare pays the physician for physician services under Part B.

We identified 9,272 questionable Part B claims for physician services provided to hospice beneficiaries in 2009. These claims were submitted by 3,116 physicians on behalf of 4,280 Medicare beneficiaries. Six of the ten physicians with the highest questionable Part B payments resided in Florida. In addition, 664 hospices were associated with Part B questionable claims. Of the 10 hospices associated with the highest questionable Part B payments, 8 were in Florida. We will refer the questionable claims to CMS for appropriate action. (OEI-02-06-00224)

Medicare > Practitioners and Suppliers > Physicians

Inappropriate Medicare Payments for Transforaminal Epidural Injection Services

Based on a medical review of a stratified random sample of 433 transforaminal epidural injection services allowed by Medicare in 2007, 34 percent did not meet Medicare requirements, resulting in approximately \$45 million in improper payments. Medicare allowed an additional \$23 million in associated facility claims for transforaminal epidural injections performed in error. In addition, services provided in offices were more likely to have a documentation error than those provided in ambulatory surgical centers or hospital outpatient departments.

Transforaminal epidural injections are a type of interventional pain management technique used to diagnose or treat pain. Transforaminal epidural injections may be used to treat pain that starts in the back and radiates down the leg, such as that from a herniated disc pressing on a nerve. Medicare Part B physician payments for transforaminal epidural injections increased from \$57 million in 2003 to \$141 million to 2007. This represents an increase of almost 150 percent.

Medicare Part B contractors are responsible for implementing program safeguards to reduce payment error. To safeguard payments, they may create local coverage determinations (LCD), implement electronic edits, or conduct medical review. We found that in 2007, 9 of 14 contractors had an LCD for transforaminal epidural injection services, but reported limited use of other safeguards. Only one contractor enforced all of its LCD requirements with edits. No contractor staff reported performing a medical review.

Based on the results of our review, we recommended that CMS conduct provider education, directly and through contractors, about proper documentation and strengthen program safeguards to prevent improper payment for transforaminal epidural injection services. In addition, we recommended that CMS take appropriate action regarding the undocumented, medically unnecessary, and miscoded services identified in our sample. CMS concurred with our recommendations and outlined steps to improve its oversight of payments for transforaminal epidural injection services. (OEI-05-09-00030)

Medicare > Practitioners and Suppliers > Medical Equipment Suppliers

Medicare Payments for Durable Medical Equipment Claims With the KX Modifier

Our reviews, which covered items with dates of service in 2007 in the four CMS-designated jurisdictions across the country, found that the KX modifier was not effective in ensuring that suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) had the required supporting documentation on file. For Medicare payment, certain DMEPOS require additional documentation in addition to a physician's order and proof of delivery. Suppliers must use the KX modifier on their Medicare claims to indicate that the claims meet Medicare coverage criteria and that the suppliers have all the required documentation on file. Our reviews included Medicare paid claims for therapeutic shoes for diabetics, continuous positive airway pressure systems, respiratory assist devices, and pressure-reducing support surfaces (groups 1 and 2) that included the KX modifier. Our specific findings follow:

• <u>Jurisdiction A</u>. Based on our sample results, we estimated that the Medicare contractor paid approximately \$54 million to suppliers that did not have the required documentation on file to support the DMEPOS items claimed. The missing documentation included proof of delivery, physicians' orders, followup documentation showing the DMEPOS items were being used or being compliantly used, sleep studies, and physicians' statements. We recommended that the Medicare contractor (1) recover approximately \$5,000 in payments for sampled DMEPOS items claimed for which the suppliers did not have the required documentation, (2) review other payments for DMEPOS related to our unallowable sampled items and recover any additional unallowable payments, (3) notify CMS of 24 suppliers that did not meet the supplier standard for maintaining proof of delivery so that CMS can take appropriate action, and (4) develop a corrective action plan to improve supplier compliance with the KX modifier and potentially save an estimated \$54 million. The contractor

concurred with our first three recommendations but did not concur with the fourth recommendation. ($\underline{A-01-09-00528}$)

• <u>Jurisdiction B.</u> Based on our sample results, we estimated that the Medicare contractor paid approximately \$55 million to suppliers that did not have the required documentation on file to support the DMEPOS items claimed. The types of missing documentation included proof of delivery, physicians' orders, use or compliant use followup documentation, sleep studies, and physicians' statements. We recommended that the Medicare contractor (1) recover approximately \$4,000 in payments for sampled DMEPOS items claimed for which the suppliers did not have the required documentation, (2) review other payments for DMEPOS related to our unallowable sampled items and recover any additional unallowable payments, (3) notify CMS of 28 suppliers that did not meet the supplier standard for maintaining proof of delivery so that CMS can take appropriate action, and (4) develop a corrective action plan to improve the effectiveness of the KX modifier and potentially save an estimated \$55 million. The contractor concurred with our recommendations.

(A-05-09-00094)

- <u>Iurisdiction C.</u> Based on our sample results, we estimated that the Medicare contractor paid approximately \$137 million to suppliers that did not have the required documentation on file to support the DMEPOS items claimed. The missing documentation included proof of delivery, physicians' orders, use or compliant use followup documentation, and physicians' statements. We recommended that the Medicare contractor (1) recover approximately \$4,500 in payments for sampled DMEPOS items claimed for which the suppliers did not have the required documentation, (2) review other payments for DMEPOS related to our unallowable sampled items and recover any additional unallowable payments, (3) notify CMS of 14 suppliers that did not meet the supplier standard for maintaining proof of delivery so that CMS can take appropriate action, and (4) develop a corrective action plan to improve the effectiveness of the KX modifier and potentially save an estimated \$137 million. The contractor acknowledged the unallowable payments and listed the corrective actions that it intended to take. (A-04-09-04039)
- <u>Jurisdiction D.</u> Based on our sample results, we estimated that the Medicare contractor paid approximately \$70 million to suppliers that did not have the required documentation on file to support the DMEPOS items claimed. The missing documentation included physicians' orders, use or compliant use followup documentation, proof of delivery, and physicians' statements. We recommended that the Medicare contractor (1) recover approximately \$6,000 in payments for sampled DMEPOS items claimed for which the suppliers did not have the required documentation, (2) review other payments for DMEPOS related to our unallowable sampled items and recover any additional unallowable payments, (3) notify CMS of the suppliers that did not meet the supplier standard for maintaining proof of delivery so that CMS can take appropriate action, and (4) develop a corrective action plan to improve the effectiveness of the KX modifier and potentially save an estimated \$70 million. The Medicare contractor concurred with our recommendations. (A-09-09-00111)

Medicare > Practitioners and Suppliers > Medical Equipment Suppliers

Medical Equipment and Supply Claims With Identical Referring Physician and Supplier National Provider Identifiers

We found that Medicare allowed \$87 million for medical equipment and supply claims with identical referring physician and supplier national provider identifiers (NPI) between May 23, 2008, and September 30, 2009.

CMS began requiring suppliers to include NPIs for the supplier and the referring physician on Medicare claims on May 23, 2008. However, CMS instituted a temporary provision allowing suppliers to use their own NPIs in the referring provider field if they could not obtain the referring physician's NPI. This review serves as a followup to a February 2009 Office of Inspector General (OIG) report that noted that the provision represents a claims-processing vulnerability. CMS's claims-processing systems did not verify that the equipment and/or supplies associated with these payments were ordered by an eligible physician, as required. We recommended in that report that CMS determine the earliest date to end the provision while maintaining beneficiary access to services. On January 3, 2011, CMS intends to implement changes to its claims-processing system that will end the temporary provision. However, the implementation date of these edits has been postponed twice. As of April 2010, nearly 2 years after the temporary provision was effective, suppliers became able to submit claims without the referring physician's NPI.

We found that Medicare payments for medical equipment and supply claims with identical referring physician and supplier NPIs were concentrated in certain Healthcare Common Procedure Coding System (HCPCS) codes and geographic locations. Ten HCPCS codes accounted for half of the \$87 million that we identified. Medicare paid for this type of claim under about 1,200 HCPCS codes during the period of our review. We also found that 10 counties represented 19 percent of the Medicare payments that we identified nationwide. In contrast, these 10 counties represented only 9 percent of Medicare payments for all medical equipment and supplies provided during the period of our review. Of the 10 counties, 3 are among the 7 areas that the Health Care Fraud Prevention and Enforcement Action Team (HEAT) have identified as areas of significant Medicare fraud.

Also, 26 percent of suppliers that received Medicare payments for claims with identical referring physician and supplier NPIs were paid by Medicare for this type of claim almost exclusively. These suppliers accounted for almost half (48 percent) of the Medicare payments we identified. Fourteen percent of suppliers that received Medicare payments for claims with identical referring physician and supplier NPIs submitted this type of claim in all 6 quarters we reviewed. These suppliers accounted for more than half (53 percent) of the Medicare payments we identified. Medicare payments for claims with identical referring physician and supplier NPIs declined over the first 7 months that the temporary provision was effective, but generally increased thereafter.

Although the \$87 million that Medicare allowed for medical equipment and supply claims with identical referring physician and supplier NPIs was permissible under the temporary CMS provision, the vulnerability remains. Therefore, we continue to believe that CMS should end the temporary provision at the earliest possible date. This report contained no recommendations. (OEI-04-10-00110)

Medicare > Practitioners and Suppliers > Medical Equipment Suppliers

A Review of Claims for Capped Rental Durable Medical Equipment

From 2006 to 2008, Medicare erroneously allowed \$2.2 million for routine maintenance and servicing of capped rental durable medical equipment (DME) and nearly \$4.4 million for repairs for capped rental DME during rental periods. We also found that in 2007, Medicare allowed nearly \$27 million for repair claims for beneficiary-owned capped rental DME that failed to meet payment requirements.

DME is medical equipment that can withstand repeated use, serves a medical purpose, is not useful in the absence of an illness or injury, and is appropriate for home use. The Deficit Reduction Act of 2005 (DRA) effectively eliminated Medicare coverage of routine maintenance and servicing for beneficiary-owned DME with rental periods that began after January 1, 2006, and Medicare has never allowed payments for maintenance and servicing or repairs for beneficiary-rented equipment. Also, Medicare should not pay for claims that lack documentation of necessity, service, or delivery, nor should it pay for repairs to DME still under manufacturer or supplier warranties.

Medicare allowed an additional \$29 million (49 percent of all allowed claims) for questionable repair claims for beneficiary-owned capped rental DME in 2007. Additionally, supplier practices adversely affected some beneficiaries with repairs exceeding \$5,000.

We recommended that CMS (1) implement an edit to deny claims for routine maintenance and servicing of capped rental DME with rental periods beginning after January 1, 2006; (2) implement an edit to deny claims for repair of beneficiary-rented capped rental DME; (3) improve enforcement of existing payment requirements for beneficiary-owned capped rental DME; (4) consider whether to require Medicare Administrative Contractors (MAC) to track accumulated repair costs of capped rental DME; (5) develop and implement safeguards to ensure that beneficiaries have access to the services they require; and (6) take appropriate action on erroneously allowed claims for maintenance and servicing, repair, and payment errors.

In its written comments on the report, CMS agreed that maintaining strong and effective controls to ensure accurate payment of capped rental DME claims is essential. CMS responded positively to each of our six recommendations and indicated that, in general, it will work to improve its comprehensive oversight of capped rental maintenance and servicing. (OEI-07-08-00550)

Part B Prescription Drugs:

Medicare > Part B Prescription Drugs > Reimbursement Policy

Comparison of Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement

Pursuant to section 1847A(d)(3) of the Social Security Act (the Act), OIG must notify the Secretary of Health & Human Services (the Secretary) if the average sales price (ASP) for a particular drug exceeds the drug's average manufacturer price (AMP) by a threshold of 5 percent. If that threshold is met, the Act states that the Secretary shall disregard the ASP for that drug and substitute the payment amount for the drug code with the lesser of the widely available market price for the drug (if any) or 103 percent of the AMP. During this semiannual period, we issued our 16th and 17th reports comparing ASPs to AMPs; however, CMS has yet to make any changes to reimbursement as a result of OIG findings.

• Comparison of Third-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2010. We identified a total of 26 HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2009. If reimbursement amounts for these 26 codes had been based on 103 percent of the AMPs, Medicare expenditures would have been reduced by \$2.7 million during the first quarter of 2010.

Of the 26 HCPCS codes that met the threshold for price adjustment, 16 had AMP data for every drug product that CMS used to establish reimbursement amounts. Of these 16 drugs, 8 were also eligible for price adjustments in one or more of the previous 4 quarters, with 3 drugs meeting the 5-percent threshold in all 5 quarters under review. The remaining 10 of 26 HCPCS codes also met the 5-percent threshold in the third quarter of 2009 but did not have AMP data for every drug product that CMS used when calculating reimbursement. We could not compare ASPs and AMPs for an additional 66 HCPCS codes because AMP data were not submitted for any of the drug products that CMS used to calculate reimbursement. Manufacturers for 16 percent of those drug products had Medicaid drug rebate agreements and were therefore generally required to submit AMPs. OIG will continue to work with CMS to evaluate and pursue appropriate actions against manufacturers that fail to submit required data. (OEI-03-10-00150)

• Comparison of Fourth-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2010. We identified 35 HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in the fourth quarter of 2009. If reimbursement amounts for these 35 codes had been based on 103 percent of the AMPs during the second quarter of 2010, Medicare expenditures would have been reduced by \$4.3 million during that quarter alone.

Of the 35 HCPCS codes that met the threshold for price adjustment, 11 had AMP data for every drug product that CMS used to establish reimbursement amounts. Of these 11 drugs, 7 were also eligible for price adjustments in one or more of the previous 4 quarters. The remaining 24 of 35 HCPCS codes also met the 5-percent threshold in the fourth quarter of 2009 but did not have AMP data for every drug product that CMS used when calculating reimbursement. We could not compare ASPs and AMPs for an additional 62 HCPCS codes because AMP data were not submitted for any of the drug products that CMS used to calculate reimbursement. Manufacturers for 16 percent of those drug products had Medicaid drug rebate agreements and were therefore generally required to submit AMPs. OIG will continue to work with CMS to evaluate and pursue appropriate actions against manufacturers that fail to submit required data. (OEI-03-10-00350)

Medicare > Part B Prescription Drugs > Manufacturer Noncompliance

Drug Manufacturers' Noncompliance With Average Manufacturer Price Reporting Requirements

In 2008, more than half of the drug manufacturers that were required to submit quarterly AMPs to CMS failed to comply with reporting requirements in at least 1 quarter. Manufacturers were even less likely to comply with monthly AMP reporting requirements, with more than three-fourths of them submitting late, incomplete, or no AMPs in at least 1 month of 2008.

Pursuant to the Social Security Act and Federal regulations, certain drug manufacturers must provide CMS with the AMP for each of their covered outpatient drugs within 30 days after the end of each month and each quarter. These AMPs play a critical role in Government payments for prescription drugs. AMPs provided quarterly by manufacturers are used to calculate drug rebate amounts under Medicaid and ceiling prices under the 340B drug program. In the future, AMPs reported monthly may be used by CMS to establish Federal upper limit (FUL) amounts in the Medicaid program and by States to set Medicaid reimbursement rates for prescription drugs. Manufacturers that fail to provide timely AMP data may be subject to Civil Monetary Penalties (CMP) and/or termination from the drug rebate program.

CMS takes action against manufacturers with missing and late quarterly AMP data, including reminding noncompliant manufacturers to submit quarterly data, terminating manufacturers that repeatedly fail to submit quarterly AMPs, and referring manufacturers with consistently late quarterly data to OIG for potential CMPs. However, CMS does not take any such action against manufacturers with missing and late monthly AMPs. Although CMS tracks manufacturers with no monthly AMP data, staff remind noncompliant manufacturers to submit overdue data only if those manufacturers initiate contact. Furthermore, CMS has yet to terminate or refer to OIG any manufacturer for failure to comply with monthly AMP reporting requirements.

To promote full compliance with quarterly and monthly AMP reporting requirements and to help ensure that Medicaid and covered 340B entities do not overpay for prescription drugs, we recommended that CMS (1) take action against manufacturers that submit incomplete quarterly AMP data and (2) take action against manufacturers that fail to submit monthly AMP data in a timely manner. CMS concurred with both recommendations and stated that it will begin referring manufacturers that submit incomplete quarterly and monthly data to OIG for CMP consideration. OIG looks forward to expanding its collaboration with CMS on administrative remedies for noncompliance with AMP reporting requirements. (OEI-03-09-00060)

End Stage Renal Disease Drugs:

Medicare > ESRD > Drug Prices

Facility Acquisition Costs and Future Medicare Payment Concerns for End Stage Renal Disease Drugs

We found that of the 11 separately billable end stage renal disease (ESRD) drugs under review (including the 2 drugs accounting for the majority of expenditures), 7 have seen a decrease in their average acquisition costs over the last several years. During this same period, the index on which CMS will soon base payment changes for ESRD drugs increased by 39 percent.

Medicare pays ESRD dialysis facilities based on a prospective payment system (PPS), known as the composite rate. Drugs not covered under the composite rate, such as epoetin alfa and darbepoetin alfa, must be billed separately and are referred to as separately billable drugs. Medicare pays for most separately billable drugs furnished by independent and hospital-based dialysis facilities at 106 percent of their ASP.

On January 1, 2011, Federal law will require CMS to begin implementation of a new system that combines composite rate payments with payments for items and services that are separately billable (including separately billable drugs) to create a single, bundled payment. Federal law will require that once the base rate for ESRD bundled payments takes effect, it be annually updated to reflect the changes over time in the prices of goods and services used to provide ESRD care. CMS has decided to base these price updates on wage and price proxy data from the Bureau of Labor Statistics (BLS). For the ESRD drugs portion of the new bundled rate, CMS plans to use the Producer Price Index (PPI) for Prescription Drugs to estimate price changes.

This report (1) compares Medicare payment amounts for selected separately billable ESRD drugs to average acquisition costs for these drugs at dialysis facilities in the first quarter of 2009, (2) examines how facility acquisition costs for selected separately billable ESRD drugs have changed over the past several years, and (3) determines whether the method that CMS plans to use to update payments for separately billable ESRD drugs after 2011 is an accurate predictor of changes in facility acquisition costs.

We found that aggregate acquisition costs for ESRD drugs at both types of dialysis facilities were below ASP-based Medicare payment amounts. We also found that if CMS had used the PPI for Prescription Drugs to update payment amounts for epoetin alfa since 2003, total program payments to all independent dialysis facilities for the drug in the first quarter of 2009 alone would have been \$113 million higher than actual payments under the current ASP-based system.

We recommend that CMS develop a more accurate method for estimating changes in the prices of ESRD drugs. CMS did not concur with our recommendation, saying that it believes that future ESRD drug price growth will more closely reflect market-based price drivers, such as those measured by the PPI for Prescription Drugs. (OEI-03-09-00280)

Medicare Contractors:

Medicare > Contractors > Information Security

Contractor Information Security Program Evaluations for Fiscal Year 2007

A CMS-contracted accounting firm's reviews of Medicare contractor information security program evaluations were adequate in scope and sufficiency, but we could not determine the extent and sufficiency of the work done for the data center technical assessments because of several issues with the working papers.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires that each Medicare contractor have its information security program evaluated annually by an independent entity. To comply with this provision, CMS contracted with a certified public accounting firm to evaluate information security programs at the MACs, FIs, and carriers. CMS also contracted with another firm to perform technical assessments at Medicare data centers.

We recommended that CMS review all contractor documentation related to future data center technical assessments and ensure that the work performed complies with CMS contractual requirements. At a minimum, this should include a review of test plans to ensure that the contractor has completed all required testing procedures and a review of contractor working papers to verify that reported gaps have been adequately supported, identified, and included in the technical assessment reports. We also recommended that CMS annually test security control areas in which a considerable number of gaps have consistently been identified in the past 2 FYs at all CMS Medicare data centers. CMS concurred with our recommendations. (A-18-07-30291)

Medicare > Contractors > Improper Payments

High-Utilization Claims for Blood-Glucose Test Strips and Lancets

Based on our sample results, we estimated that the DMEPOS MAC for Jurisdiction A inappropriately allowed for payment of approximately \$49.2 million in claims for CY 2007 for home blood glucose test strip and/or lancet supplies (test strips and lancets) that we identified as high-utilization claims. We estimated that the contractor inappropriately paid approximately \$39.2 million of this amount to DME suppliers. The contractor could have saved Medicare an estimated \$39.2 million for CY 2007 if it had controls to ensure that claims for test strips and/or lancets complied with certain Medicare documentation requirements.

Medicare Part B covers test strips and lancets that physicians prescribe for diabetics. Medicare utilization guidelines allow up to 100 test strips and 100 lancets every month for insulin-treated diabetics and every 3 months for non-insulin-treated diabetics. Additional requirements apply for reimbursement of a claim for a quantity of test strips and lancets that exceeds the utilization guidelines (high-utilization claim).

To help achieve potential savings in future years, we recommended that the contractor (1) implement system edits to identify high-utilization claims for test strips and/or lancets and work with CMS to develop cost-effective ways of determining which claims should be further reviewed for compliance with Medicare documentation requirements; (2) implement system edits to identify claims for test strips and/or lancets that have overlapping service dates; and (3) enforce Medicare documentation requirements for claims for test strips and/or lancets by identifying DME suppliers with a high volume of high-utilization claims, performing prepayment reviews of those DME suppliers, and referring them to OIG or CMS for further review or investigation when necessary. The contractor provided information on actions that it had taken to address our recommendations. (A-09-08-00043)

Medicare > Contractors > Overpayment Identification and Referral

Overpayments Identified by Program Safeguard Contractors

PSCs, which are engaged by CMS to conduct a variety of activities to ensure the integrity of Medicare payments, referred \$835 million in overpayments to claims processors for collection in 2007. However, of 18 PSCs, only 2 were responsible for 62 percent of the amount. Moreover, the amount of overpayment dollars that PSCs referred for collection was not always related to the size of PSCs' oversight responsibility.

PSCs' identification and referral of overpayments to claims processors for collection is an important PSC activity because it can lead to the recovery of funds for the Medicare program. In this report, we identified the number, dollar amount, and claim type of Medicare overpayments that PSCs referred to claims processors for collection in CY 2007. This report and its companion report (summarized below), *Collection Status of Medicare Overpayments Identified*

by Program Safeguard Contractors, OEI-03-08-00030, are our response to a request from a committee of the U.S. House of Representatives.

All 18 PSCs referred 4,239 overpayments to claims processors for collection in 2007. PSCs differed substantially in the dollar amount of overpayments that they referred for collection in 2007. PSCs referred from \$3 million to \$266 million in overpayments for collection, with a median of \$15 million. We also found that, while Part B payments represented 29 percent of PSCs' oversight responsibility (\$87 billion of \$296 billion), Part B overpayments accounted for 89 percent of PSCs' overpayment dollars referred for collection (\$747 million of \$835 million). Part A payments represented 71 percent of PSCs' oversight responsibility (\$209 billion of \$296 billion), and Part A overpayments accounted for 11 percent of PSCs' overpayment dollars referred for collection (\$88 million of \$835 million).

CMS is transitioning PSCs to seven Zone Program Integrity Contractors (ZPIC). Each ZPIC will be responsible for all claim types in its geographic zone.

We recommended that CMS determine why certain PSCs have low levels of overpayment dollars referred for collection, considering their broad oversight responsibility. We also recommended that CMS determine why certain PSCs have low Part A overpayment dollars referred for collection compared with their Part B overpayment dollars referred for collection. CMS concurred with both recommendations and stated that the change to the new ZPIC contracting strategy should address OIG's concerns. (OEI-03-08-00031)

Medicare > Contractors > Overpayment Recoveries

Collection Status of Medicare Overpayments Identified by Program Safeguard Contractors

Overpayments referred for collection by PSCs in 2007 did not result in significant recoveries to the Medicare program. PSCs referred 4,239 overpayments totaling \$835 million to claims processors in 2007, but only 7 percent (\$55 million of \$835 million) had been collected by claims processors as of June 2008. Of the \$55 million collected, 27 percent was for Part A claims; 56 percent was for Part B claims excluding DMEPOS; and 17 percent was for Part B DMEPOS claims.

In this report, we determined the collection status, as of June 2008, of overpayments referred by PSCs for collection in CY 2007. At the time of our review, PSCs were not required to keep track of the amount claims processors collect on PSC overpayment referrals. CMS is transitioning PSCs to seven ZPICs and is providing ZPICs an incentive to keep track of the amount claims processors collect on ZPIC overpayment referrals. CMS is now providing incentives to claims processors to provide collection information to ZPICs. According to CMS staff, CMS also expects ZPICs in high-fraud regions to focus on quick response to fraud and administrative actions.

As of June 2008, 53 percent (\$446 million) of the \$835 million in overpayment dollars that PSCs referred to claims processors for collection in 2007 was sent to the Department of the Treasury's cross-servicing program for collection. However, this program does not have a high rate of return. Claims processors reported that collection was not complete for \$40 million, or 5 percent of the \$835 million in overpayments that PSCs referred for collection. Another 5 percent of the PSC overpayment dollars likely will not be collected by claims processors because the provider stopped billing, filed bankruptcy, went out of business, or was deceased. Collection was on hold, pending investigation or appeal for 17 percent of the PSC overpayment dollars. As of June 2008, 6 percent of the PSC overpayment dollars was no longer owed by providers because of revisions claims processors made to overpayment collection amounts and appeal decisions that were favorable to providers. Finally, claims processors could not provide data for one of four PSC overpayment referrals, which accounted for 8 percent of the PSC overpayment dollars. Claims processors reported that they did not receive or that they could not provide any collection information for 1,060 of 4,239 overpayments.

We recommended that CMS regularly collect all necessary information to determine the overpayments PSCs and ZPICs refer to claims processors for collection, the collection status of these overpayments, and the percentage of overpayments in each category of collection status. We also recommended that CMS require that PSCs, ZPICs, and claims processors have controls in their tracking systems to ensure that all overpayment referrals and data related to their collection status can be found. CMS should also determine what happened to the 1,060 overpayments that PSCs referred to claims processors in 2007, for which claims processors could not provide any collection information. CMS concurred with all three recommendations. (OEI-03-08-00030)

Medicare > Contractors > Overpayment Recoveries

Collection Rate for Overpayments Made to Medicare Suppliers in South Florida

We found that the collection rate of PSC-identified DMEPOS overpayments in South Florida was only 1 percent. This is compared with a national collection rate for all claim types of 7 percent and a national DMEPOS collection rate of 3 percent as identified in the study, *Collection Status of Medicare Overpayments Identified by Program Safeguard Contractors* (OEI-03-08-00030), described above.

For this memorandum report, we conducted further analysis on data obtained during the earlier study. Previous OIG work has identified south Florida (Miami-Dade, Broward, and Palm Beach counties) as an area vulnerable to DMEPOS fraud and abuse. Therefore, we focused our additional analysis on PSC-identified DMEPOS overpayments in south Florida.

The median overpayment was \$527,420 and 25 percent of the overpayments were more than \$1 million each. While only 1 percent of the PSC-identified DMEPOS overpayment dollars in south Florida was collected, another 91 percent was referred for collection to the Department of the Treasury which historically does not have a high rate of return. In addition, by December

2008, only 1 of the 315 suppliers associated with south Florida DMEPOS overpayments was still

active in the Medicare program; the remaining suppliers were either revoked or inactive. The fact that these suppliers are no longer billing the Medicare program makes overpayment collection difficult.

Given that south Florida DMEPOS overpayments identified by the PSC resulted in low returns for the Medicare program, we concluded that overpayment identification and collection may not be the most effective program integrity tool for DMEPOS claims especially in south Florida and other high-fraud areas. Ensuring that claims are legitimate and appropriate before payment would eliminate the need to expend resources for postpayment collection efforts that are not likely to yield high returns. (OEI-03-09-00570)

Medicare > Contractors > Overpayment Recoveries

Payments to Providers Terminated From the Medicare Program

In two reviews, we found that Medicare contractors did not always recover overpayments for services furnished on or after the effective termination dates of provider Medicare agreements or during termination-related Denial of Payment for New Admissions (DPNA) sanction periods. CMS can impose DPNA sanctions on skilled nursing facilities (SNF) that fail to comply with Medicare requirements. Payments for services provided on or after the termination date of a provider agreement or for services provided to beneficiaries initially admitted during a DPNA sanction period are generally not allowable. The results of our reviews, which covered providers terminated between January 1, 2003, and January 31, 2007, follow:

- For 5 of the 64 terminated providers whose payments we reviewed, the contractor had not recovered \$1.2 million in overpayments that were subject to recovery. The contractor had not recovered \$1.16 million of this total because it did not follow its procedures to retroactively identify payments for post-termination services. The contractor had not recovered the remaining \$62,000 because it had not yet implemented written DPNA-related procedures. The contractor confirmed that the overpayments were subject to recovery. We recommended that the contractor recover the \$1.2 million in overpayments and follow its procedures to retroactively identify and recover overpayments for services furnished on or after the providers' effective termination dates. The contractor agreed with our recommendations and said that it was recovering the overpayments.

 (A-05-09-00035)
- For 11 of the 262 terminated providers whose payments we reviewed, the contractor had not recovered \$2 million in overpayments that were subject to recovery. The contractor had not recovered the overpayments because it did not follow its procedures to retroactively identify payments for post-termination services. The contractor confirmed that the overpayments were subject to recovery. We recommended that the contractor recover the \$2 million in overpayments and follow its procedures to retroactively identify and recover

overpayments for services furnished on or after the providers' effective termination dates. The contractor agreed with our recommendations. (A-05-09-00076)

Medicare > Contractors > Overpayment Recoveries

Dates of Service After Beneficiaries' Deaths

Based on our sample results, we estimated that CMS did not identify and recover \$8.2 million in overpayments for Medicare Part B claims with dates of service after the beneficiaries' deaths. CMS did not make or had already recovered overpayments for Medicare claims on behalf of 96 of the 150 deceased beneficiaries in our sample, including all of the Part A claims sampled. However, CMS did not identify and recover all overpayments for Part B (DME and physician/supplier) claims with dates of service after the 54 remaining sampled beneficiaries' deaths.

Federal regulations state that Medicare will not pay for any expenses incurred for items or services that are not reasonable and necessary. Because medically necessary services cannot be provided after a beneficiary dies, payments for claims with dates of service after a beneficiary's death are overpayments. Because of the inherent difficulties in receiving timely and accurate information from third parties, Medicare makes overpayments for claims for services, equipment, and supplies with dates of service after beneficiaries' deaths. To identify such overpayments, CMS requires its PSCs to perform annual deceased-beneficiary postpayment reviews. The PSCs obtain data for these reviews from their own beneficiary eligibility records or from CMS deceased-beneficiary files, which contain the dates of death for all beneficiaries who died in the preceding 2 calendar years.

We recommended that CMS (1) recoup \$15,000 in overpayments identified in our sample, (2) use our Part B data to identify and collect potential overpayments estimated at \$8.2 million for the nonsampled beneficiaries, (3) provide PSCs with complete date-of-death information, (4) correct the CWF process to ensure that dates of death from home health claims are entered in the CWF, (5) work with the Social Security Administration to obtain verified dates of death to assist in identifying overpayments, and (6) establish a CWF edit to check all prior claims for a deceased beneficiary for overpayments once a date of death is added to the CWF. CMS concurred with our recommendations. (A-01-09-00519)

Medicare > Contractors > Analysis of Errors

Analysis of Errors Identified in the Fiscal Year 2009 Comprehensive Error Rate **Testing Program**

We found that 6 types of health care providers accounted for \$4.4 million, or 94 percent, of the \$4.7 million in improper payments identified by CMS's CERT contractor for FY 2009. The provider types were inpatient hospitals, DME suppliers, hospital outpatient departments, physicians, SNFs, and home health agencies (HHA).

As part of the Medicare error rate process, CMS's CERT contractor conducted medical record reviews of a random sample of paid claims from all types of providers. Based on the results of those reviews, CMS reported to Congress that the national Medicare error rate for FY 2009 was 7.8 percent, or \$24.1 billion. The Improper Payments Information Act of 2002 (IPIA) requires

Our analysis of the erroneous claims identified by the CERT contractor found that 3 types of errors accounted for about 98 percent of the \$4.4 million in improper payments attributable to the 6 types of providers:

- insufficient documentation, e.g., missing clinical notes or test results and missing, incomplete, or illegible physician orders, which resulted in improper payments totaling \$2.6 million;
- miscoded claims, which resulted in improper payments totaling \$0.9 million; and

that CMS estimate improper Medicare fee-for-service (FFS) payments each year.

• medically unnecessary services and supplies, which resulted in improper payments totaling \$0.8 million.

We recommended that, as part of its analysis of the FY 2009 CERT improper payments, CMS use the results of our analysis in identifying (1) the types of payment errors indicative of programmatic weaknesses and (2) any additional corrective actions needed to strengthen the CERT program. CMS concurred with our recommendation. (A-01-10-01000)

Medicare Part D (Prescription Drug Program)

Medicare > **Part** D > **Prescriber Identifiers**

Invalid Prescriber Identifiers on Medicare Part D Drug Claims

OIG found that \$1.2 billion in Medicare Part D prescription drug claims contained invalid prescriber identifiers in 2007. Invalid identifiers were used on more than 18 million prescription drug claims. These identifiers either (1) were not listed as valid identifiers in the NPI, Drug Enforcement Administration (DEA) number, or Unique Physician Identification Number (UPIN) registry databases or (2) had been deactivated or retired before January 1, 2006.

Part D drug plans must submit an electronic record to CMS for each covered prescription filled for their enrollees. This electronic record, called a prescription drug event (PDE) record, contains drug cost and payment data fields that enable CMS to make payments to plans and oversee the Part D benefit. CMS requires that PDE records contain an identifier for the drug's prescriber. Identifiers that may be used include NPIs, DEA numbers, and UPINs. Each type of prescriber identifier has specific length and format requirements. For 17 percent of the PDE records that contained invalid prescriber identifiers, the identifiers did not conform to length or format specifications. These PDE records represented \$213 million in payments by Medicare drug plans and enrollees in 2007.

Our review also revealed that 10 of 527,749 invalid identifiers accounted for 17 percent of all drug claims with invalid prescriber identifiers in 2007. Medicare Part D plans and enrollees paid pharmacies \$237 million in 2007 for drug claims that contained these 10 invalid identifiers. Of the top 10 invalid prescriber identifiers, 1 was recorded on almost 1.8 million PDE records for more than 150,000 beneficiaries enrolled with 248 different Medicare drug plan sponsors. These plan sponsors and enrollees paid pharmacies almost \$105 million for drug claims with this single invalid identifier. Of the top 10 invalid identifiers, 5 appeared on individual claims for very expensive drugs, with payment amounts totaling more than \$10,000 per claim. The majority of PDE records that contained one of the top 10 invalid prescriber identifiers were submitted by a single large pharmacy benefit manager and mail-order pharmacy.

Prescriber identifiers are valuable Part D program safeguards. These identifiers are the only data on Part D drug claims to indicate that legitimate practitioners have prescribed medications for Medicare enrollees. Based on our findings, we concluded that CMS and Part D plans do not have adequate procedures in place to detect invalid values in the prescriber identifier field. To address this vulnerability, we recommended that CMS conduct periodic reviews to ensure the validity of prescriber identifiers used on PDE records. We also recommended that CMS require Part D plans to institute procedures to (1) identify invalid identifiers in the prescriber identifier field on Part D drug claims and (2) flag for review Part D drug claims that contain invalid identifiers in the prescriber identifier field. CMS concurred with our recommendations. (OEI-03-09-00140)

Medicare > Part D > Less-Than-Effective Drugs

Less-Than-Effective Medicare Part D Drugs

Of approximately \$115 billion in gross drug costs included in Medicare Part D sponsors' PDE data for CYs 2006 and 2007, CMS accepted PDE data totaling \$43.3 million associated with less-than-effective drugs. Pursuant to Federal requirements, Medicare Part D should not have covered these drugs. Less-than-effective drugs are drugs that the Food and Drug Administration (FDA) approved before 1962 and that FDA subsequently found to be less than effective.

CMS's Drug Data Processing System subjects sponsors' PDE data to an edit designed to reject less-than-effective drugs. Although the edit identified and rejected the vast majority of PDE data associated with less-than-effective drugs, the edit did not identify and reject PDE data for some less-than-effective drugs because the Part D program used an incomplete list of less-than-effective drugs as the basis for the edit. There is no definitive list of less-than-effective drugs.

We recommended that CMS (1) determine whether it can impose financial adjustments on sponsors that were paid for furnishing less-than-effective drugs and (2) help ensure that drugs covered by Medicare Part D comply with Federal requirements by collaborating with FDA to create and maintain a comprehensive list of less-than-effective drugs, regularly disseminating this list to all sponsors, and using this list to reject PDE data for less-than-effective drugs.

CMS agreed with our first recommendation and partially disagreed with our second recommendation, stating that FDA should be responsible for maintaining and disseminating the list of less-than-effective drugs. We modified our second recommendation to reflect FDA's

Other Medicare-Related Reviews

role in identifying less-than-effective drugs. (A-07-09-04138)

Other Reviews > Program Integrity > Adverse Actions

CMS Reporting to the Healthcare Integrity and Protection Data Bank

Although CMS took adverse actions, it did not report all of the actions to the Healthcare Integrity and Protection Data Bank (HIPDB) as required. CMS takes several types of adverse actions that are required to be reported to the HIPDB, including revocations and suspensions of laboratory certifications; terminations of providers from participation in Medicare; and CMPs against all types of providers, managed care plans, and prescription drug plans.

The HIPDB is a national data bank administered by the Health Resources and Services Administration (HRSA) that contains reports of adverse actions against health care practitioners, providers, and suppliers. The HIPDB plays an important role in preventing the employment of fraudulent or abusive health care providers, so it is important that the information it contains be complete and accurate. Federal and State government agencies and health plans are required to report certain adverse actions to the HIPDB. The Social Security Act defines the types of adverse actions that must be reported to the HIPDB. These include licensure and certification actions, exclusions from participation in Federal and State health care programs, criminal convictions, civil judgments related to health care, and any other adjudicated actions or decisions that the Secretary establishes by regulation.

CMS failed to report 148 adverse actions imposed against laboratories in 2007 and 30 adverse actions imposed against managed care and prescription drug plans between January 1, 2006, and July 31, 2009. None of the adverse actions against DME suppliers taken after 2008 had been reported to HIPDB at the time of our review; however, as of April 30, 2009, the HIPDB contained 5,125 adverse actions against DME suppliers imposed from 1998–2008. None of the 45 nursing homes terminated from participating in Medicare from 2004 through 2008 were reported to the HIPDB until 2009, well after the required reporting timeframe. The Division of National Systems, the group within CMS responsible for reporting adverse actions against certified provider types, did not report any actions between 2001 and 2008.

We recommended that CMS report all adverse actions to the HIPDB as required. To accomplish this, CMS should educate staff and contractors about the types of adverse actions required to be reported and the timeframes for reporting. In its written comments on the report, CMS concurred with our recommendation. CMS described planned efforts to report adverse actions imposed against nursing facilities, laboratories, and DME suppliers, including working with

HRSA to develop technical procedures and educating staff and contractors about HIPDB reporting. (OEI-07-09-00290)

Other Reviews > Beneficiary Rights > Language Access

Guidance and Standards on Language Access Services

The Office for Civil Rights' (OCR) guidance and the Culturally and Linguistically Appropriate Services in Health Care (CLAS) standards address the provision of language access services. OCR guidance recommends a four-factor assessment to help determine what language access services to offer. The Office of Minority Health's (OMH) CLAS standards can help providers become responsive to the cultural and linguistic needs of diverse populations. Four of the fourteen CLAS standards focus on the provision of language access services. These standards are (1) providing services during all business hours, (2) providing verbal offers and written notices of rights to services, (3) assuring the competence of language assistance provided by staff, and (4) providing written materials and signage translated into appropriate languages. Language access services are designed to promote effective communication between Limited English Proficient (LEP) persons and non-LEP persons. Language access services can include oral interpretation; written translation; and other provisions that enhance communication, such as translated signs. The lack of language access services enables communication barriers to persist between LEP persons and non-LEP persons.

- Medicare Providers. Sixty-nine percent of Medicare providers conducted the four-factor assessment recommended by OCR guidance when determining what language access services to offer. However, only 33 percent of Medicare providers offered services consistent with all four of OMH's CLAS standards on language access services. Seventy-three percent of providers reported benefits to offering language access services and 54 percent reported obstacles. Few providers reported data on the costs of providing language access services and the data provided were not comparable. To improve Medicare providers' awareness and implementation of CLAS standards and to help providers offer language access services, we recommended that (1) OCR inform providers about OMH's CLAS standards, (2) OMH increase outreach to providers to familiarize them with CLAS standards, and (3) OMH offer model translated written materials and signs to providers. OCR and OMH concurred with our recommendations. CMS indicated that it did not have any substantive comments. (OEI-05-10-00050)
- Medicare Plans. Eighty-eight percent of Medicare plans conducted the four-factor assessment recommended by OCR guidance when determining what language access services to offer. Only sixty-seven percent of Medicare plans offered services consistent with all four of OMH's CLAS standards on language access services, largely because Medicare plans did not verbally inform LEP persons of their right to language access services. Forty-nine percent of Medicare plans reported benefits to offering language access services and 57 percent reported obstacles. We could not compare data on the costs of providing language access services because plans use different methods to calculate costs.

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We recommended that OMH collaborate with CMS to inform Medicare plans that they should notify LEP persons both verbally and in writing of their right to receive language access services. CMS has an established infrastructure for communicating with Medicare plans. OMH and CMS both concurred with our recommendation. (OEI-05-10-00051)